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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/014,320	12/11/2001	Siamak Tabibzadeh	50425/137	1488				
7590 06/05/2007								
Craig J. Arnold Amster, Rothstein & Ebenstein 90 Park Avenue New York, NY 10016		<table border="1"><tr><td>EXAMINER</td></tr><tr><td>YAEN, CHRISTOPHER H</td></tr></table>			EXAMINER	YAEN, CHRISTOPHER H		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/014,320	Applicant(s) TABIBZADEH, SIAMAK	
	Examiner Christopher H. Yaen	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 11-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/30/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: TABIBZADEH, SIAMAK

Election/Restrictions

1. Applicant's election with traverse of group I (claims 9-10) in the reply filed on 3/30/2007 is acknowledged. The traversal is on the ground(s) that the search for additional groups would not be burdensome to the examiner. Specifically applicant has indicated that the search for additional groups would not be burdensome to the examiner because the search for the groups would provide overlapping search results. This is not found persuasive because the search for a method of detecting proteins does not coincide with a search for a method of detecting polynucleotide. As indicated in the previous office action, a search for a method of detecting a nucleotide sequence does not necessarily produce a search for a method of detecting a protein. Moreover, the two methods have been classified in different classes and subclasses. Therefore a search of both groups would be burdensome. Applicant is also reminded that the inventions of group I and II are linked by claims 1-8. If the subject matter of linking claims 1-8 is deemed allowable, the restriction requirement between groups I and II will be withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-26 are pending, claims 11-26 are with drawn from further consideration as being drawn to non-elected subject matter.

2. Claims 1-10 are examined on the merits. For prior art purposes, claims 1-8 are examined to the extent that the claims read on a method of detecting using an antibody as the detecting agent.

Information Disclosure Statement

3. The Information Disclosure Statement filed on 3/30/2007 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 112, 1st paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A WRITTEN DESCRIPTION REJECTION.

The written description in this case only sets forth a method of detecting an ebaf protein of SEQ. ID No: 2 and therefore the written description is not commensurate in scope with the claims which read on a method of detecting an ebaf protein

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encompassed by the term "ebaf" as disclosed in the specification as filed. The term "ebaf" encompasses proteins not in possession of the applicant at the time of filing.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the claimed genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See *University of Rochester v. G.D. Searle & Co., Inc.*, F.3d, 2004 WL 260813, at 9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus of ebaf proteins. That is, the specification has indicated that the

term “ebaf” encompasses both wild type ebaf/leftyA (i.e. SEQ. ID No: 2), analogues of ebaf which are at least 60% identical to ebaf, leftyB, lefty1, lefty2, and other proteins which have sequence similarities to ebaf/leftyA. (see page 10, for example). The genus of proteins encompassed is highly variant and inclusive of numerous structural variants between genus members. Further, the specification and the claims provide no guidance on structure of variants that would have the same functional properties as ebaf/leftyA. Therefore, without specific guidance, one would not know exactly which polypeptides are encompassed by the claimed genus. The disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus are highly variant, the disclosure of the term ebaf/leftyA is insufficient to describe the genus. The general knowledge and the level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed.

“[G]eneralized language may not suffice if it does not convey the detailed identity of an invention.” *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Furthermore, the Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568). In this instance, as in that, there is no language that adequately describes with the requisite degree of particularity necessary to satisfy the written

description requirement the genus of structurally variable polypeptides encompassed by the term ebaf. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1,4, and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tabibzadeh *et al* (Mol. Human Reprod.; 1998; 4(6):595-602). Tabibzadeh *et al* teach a method of detecting the presence of ebaf polypeptide comprising obtaining endometrial tissue from a biopsy and from hysterectomy specimens from a normal fertile female (see page 596), contacting the sample with a polyclonal antibody specific against ebaf polypeptide (see page 597), and detecting the binding of the polyclonal antibody to said ebaf polypeptide (see page 597). Specifically, Tabibzadeh *et al* teach that the detection of the protein is accomplished by using either Western blotting (see page 596-597) or immunohistochemical staining (see page 598).

8. Claims 1,4, and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tabibzadeh S (WO 99/55902). Tabibzadeh S teaches a method of detecting the

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presence of ebaf polypeptide comprising obtaining a endometrial tissue from a human (see page 39), contacting the sample with an affinity purified antibody against the C-terminal end of ebaf, and detecting the binding of said antibody to the said polypeptide (see page 42, for example). It is also disclosed that the method can be accomplished by an ELSIA (see page 71, for example), a Western blot (see page 42, for example) or by immunohistochemistry (see page 43, for example). Tabibzadeh S also teaches that the method can further comprise contacting the antibody against ebaf with "100 fold excess of peptide" (see page 71, for example).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabibzadeh *et al* (Mol. Human Reprod. 1998; 4(6):595-602-herein Tabibzadeh #1) or

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Tabibzadeh S (WO 99/55902-herein Tabibzadeh #2) in view of Tabibzadeh *et al* (Frontiers in Bioscience 1997; 2:a18-25- herein Tabibzadeh #3).

- a. The teachings of Tabibzadeh #1 and Tabibzadeh #2 are set forth above as they apply to claims 1,4, and 7-10. Both Tabibzadeh #1 and #2 do not specifically teach the different types of epithelial cells as claimed. However, this deficiency is remedied by the teaching of Tabibzadeh #3.
- b. Tabibzadeh #3 teach the examination of various tumor and normal tissue for the expression of ebaf. Various cancerous tissue samples all of which are derived from epithelial cells are determined to express ebaf.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to detect any epithelial based tumor for the expression of ebaf protein using an antibody that specifically binds to ebaf, because the prior art provides sufficient motivation to modify and substitute the endometrial tissue as provided by Tabibzadeh #1 and #2 with any form of epithelial based cancer such that the detection of ebaf would be indicative of a neoplastic lesion. Those of skill would have a reasonable expectation of success in doing so because Tabibzadeh #3 has already provided a list of epithelial based tumors which have shown elevated levels of ebaf expression.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER H. YAEN
PRIMARY EXAMINER

Art Unit 1643
May 28, 2007